



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/966,522 | 09/28/2001 | Thomas Krahn | Bayer 10,139.3-KGB | 5606 |

27384 7590 10/01/2004

NORRIS, MCLAUGHLIN & MARCUS, PA
875 THIRD STREET
18TH FLOOR
NEW YORK, NY 10022

EXAMINER

DO, PENSEE T

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,522

Applicant(s)

KRAHN ET AL.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 24-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date July 14, 2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on July 14, 2004 has been acknowledged and entered.

Information Disclosure Statement

The IDS filed on July 14, 2004 has been acknowledged and entered.

Election/Restrictions

Applicant's election with traverse of group II, claims 17-23 in the reply filed on July 14, 2004 is acknowledged. The traversal is on the ground(s) that the novel and unobvious combination of a fluorescent dye and a masking dye presents every single claim on file. Thus, if the elected subject matter is allowable, then it means that each and every claim present on file is novel and unobvious over prior art for exactly the same reason. This is persuasive.

Remarks

Claim 21 has been indicated allowable in the previous office action. However, the rejection regarding claim 21 had been discussed in 35 USC 102(e) by Cubbage towards the end of the rejection. Since there is a discrepancy regarding the rejection of claim 21, claim 21 is indicated rejected under the maintained rejection 102(e).

Withdrawn Rejection(s)

Rejection under 35 USC 112, 2nd paragraph is withdrawn herein.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1641

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification of the present invention fails to support or describe that fluorescent dye is Brilliant Black. The specification describes Brilliant black as a masking dye only.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cubbage et al. (US 5,582,982) in view of Van Aken (US 5,489,537).

Cubbage is discussed below.

However, Cubbage fails to teach Brilliant Black as a fluorescent dye.

Van Aken teaches a method and kit for determining the presence or absence of a substance by detection of a colloidal dye associated with agglutinated particles. The colloidal dye is a background-enhancing dye, which reduces non-specific background to

Art Unit: 1641

enhance optical detection. The background-enhancing dye is a water-soluble dye such as Brilliant Black. (see col. 21, lines 58-67).

It would have been obvious to one of ordinary skills in the art to use Brilliant Black as a fluorescent dye in the kit for use in the method of Cubbage because both references teach using fluorescent dye, which reduces background light in assay. Since Brilliant Black is known for enhancing the background in an assay, which uses optical detection, it would motivate one of ordinary skills in the art to use Brilliant Black in assays such as one taught by Cubbage because Cubbage teaches using fluorescent label, which is known for producing non-specific background.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-21, 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Cubbage et al. (US 5,582,982).

Cubbage et al. teach a kit comprising a fluorescent probe and a background-reducing compound. The background-reducing compound comprises a light-absorbing moiety with a structure different than that of the fluorescent dye moiety of the

Art Unit: 1641

fluorescent probe and having an absorption wavelength range that includes of the emission wavelengths of the fluorescent probe at which the amount of light is measured. If the amount of light emitted exceeds a certain specified amount, the cell is considered to have target molecules. The background-reducing compound will absorb emissions from the fluorescent probe. In addition, the background-reducing compound will absorb light emitted due to autofluorescence by non-probe molecules present in the biological entity. Background-reducing compounds may be staining dyes, such as azo dye derivatives. (See also col. 2, line 45-col. 7, line 27). Regarding the functional limitations such as the masking dye is present in solution at an amount sufficient to reduce non-specific background light emitted from said solution by at least 15%, 30%, 50% or 70% compared to the non-specific background light emitted from said solution in the absence of said masking dye, if the masking dye in Cubbage has an absorption spectrum that overlaps with the emission and/or excitation spectrum of said fluorescent dye, then the masking dye would inherently reduce non-specific background by at least 15%, 30%, 50% or 70%. Thus, the masking dye in Cubbage would inherently improve the optical signal-to-noise ratio by at least 300%. Regarding the limitation that the fluorescent dye detects a voltage across the membrane of the biological cell, it is inherent that Cubbage teaches these limitations because if the fluorescent dye were present, then it would comprise all the functional limitation such as detecting the voltage across the membrane of the biological cell.

Response to Arguments

Applicant's arguments filed July 14, 2004 have been fully considered but they are not persuasive.

Applicant submits that since claim 17 recites that "the masking is substantially impermeant to the membrane of the biological cell" and Cubbage teaches that "the background-reducing compound will diffuse onto and into the biological entity", the 102(e) rejection under Cubbage is invalid.

First, the limitation of "the masking is substantially impermeant to the membrane of the biological cell" is a functional limitation of the composition being claimed. Since Applicants fail to define specific masking dye, any masking dye in the reference would satisfy the requirement of a masking dye. And if such masking dye reduces non-specific background when combined with a fluorescent dye, then it would have other functional limitations such as being impermeant to the biological cell. Furthermore, since the claim recites "the masking dye is ***substantially impermeant*** to the membrane..", it is interpreted as ***some*** of the masking dye is permeable to the membrane of the biological cell. Thus, the background-reducing compound of Cubbage is still relevant to the claimed masking dye of the present invention. Thus, the 102(e) rejection by Cubbage still maintains.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0923. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
September 24, 2004

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641
9/29/04